



Practitioner's Docket No.

2001-IP-005443U2

PATENT

IPW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bradley L. Todd et al.

Application No: 10 / 650,101

Group No.: 1712

Filed: 08/26/2003

Examiner: Zimmer Marc S

For: Compositions and Methods for Reducing The Viscosity of A Fluid

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT BEFORE MAILING DATE OF EITHER A FINAL ACTION OR NOTICE OF ALLOWANCE (37 C.F.R. § 1.97(c))

NOTE: 37 C.F.R. 1.97: "(c) An information disclosure statement shall be considered by the Office if filed after the period specified in paragraph (b) of this section, provided that the information disclosure statement is filed before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application, and it is accompanied by one of:

(1) The statement specified in paragraph (a) of this section; or

(2) The fee set forth in § 1.17(p)."

NOTE: "If a final action or notice of allowance is mailed in an application and later withdrawn, the application will be considered as not having had a final action or notice of allowance mailed for purposes of considering an information disclosure statement." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10*

(When using Express Mail, the Express Mail label number is mandatory;

Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

☒ deposited with the United States Postal Service in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

37 C.F.R. § 1.8(a)

37 C.F.R. § 1.10 *

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Chasidy Smith
Signature

Date: 8-17-05

Chasidy Smith

(type or print name of person certifying)

* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

(Transmittal of Information Disclosure Statement before Mailing Date of Either a Final Action Or Notice of Allowance [8-4]—page 1 of 3)

NOTE: 37 C.F.R. § 1.704(d): "A paper containing only an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraphs (c)(8), (c)(9), (c)(9), or (c)(10) of this section if it is accompanied by a statement that each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement. This thirty-day period is not extendable."

NOTE: "If information submitted during the period set forth in 37 C.F.R. 1.97(c) with a certification is used in a new ground of rejection on unamended claims, the next Office action will not be made final since in this situation it is clear that applicant has submitted the information to the office promptly after it has become known and the information is being submitted prior to a final determination on patentability by the Office. However, the information submitted with a certification can be used in a new ground of rejection and the next Office action made final, if the new ground of rejection was necessitated by amendment of the application by applicant. Where the information is submitted during this period with a fee, the examiner may use the information submitted, e.g., printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. See MPEP 708.07(a). If a new ground of rejection is introduced that is neither necessitated by an amendment to the claims nor based on the information submitted with the fee set forth in 37 C.F.R. § 1.17(b), the Office action shall not be made final." Notice of April 20, 1992 (1138 O.G. 37-61, 38).

WARNING: "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. § 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63). But see § 103(b) and (c), limited suspension of action in a continued prosecution application (CPA) filed under § 1.53(d) and in a request for continued examination (RCE) under § 1.114.

WARNING: No extension of time can be had under 37 C.F.R. 1.136 (a) or (b) for filing an IDS. 37 C.F.R. 1.97(f).

TIME OF TRANSMITTAL OF ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

1. The information disclosure statement transmitted herewith is being filed after three months of the filing date of this national application or the date of entry of the national stage as set forth in § 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but before the mailing date of either:
 - (1) a final action under § 1.113 or
 - (2) a notice of allowance under § 1.311,whichever occurs first.

STATEMENT OR FEE

2. Accompanying this transmittal is

(check either A or B below)

- A. ☒ a statement as specified in 37 C.F.R. § 1.97(e).

OR

- B. ☐ the fee set forth in 37 C.F.R. § 1.17(p) for submission of an information disclosure statement under § 1.97(c). (\$180.00).

(Transmittal of Information Disclosure Statement before Mailing Date of Either a Final Action Or Notice of Allowance. [8-4]—page 2 of 3)

FEE PAYMENT

(complete this item, if applicable)

3. Applicant elects the option to pay the fee set forth in 37 C.F.R. § 1.17(p) for submission of an information disclosure statement under § 1.97(c) (\$180.00).

Fee due \$ _____

METHOD OF PAYMENT OF FEE

4.

- ☐ Attached is a ☐ check ☐ money order in the amount of \$ _____
- ☐ Authorization is hereby made to charge the amount of \$ _____
- ☐ to Deposit Account No. _____
- ☐ to Credit card as shown on the attached credit card information authorization form PTO-2038.

WARNING: Credit card information should not be included on this form as it may become public.

- ☐ Charge any additional fees required by this paper or credit any overpayment in the manner authorized above.

A duplicate of this paper is attached.



SIGNATURE OF PRACTITIONER

Reg. No. 28,6266

Robert A. Kent

(type or print name of practitioner)

Tel. No.: (580) 251-3125

P.O. Box 1431

P.O. Address

Customer No.:

Duncan, OK 73536-0440

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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STATEMENT FOR INFORMATION DISCLOSURE UNDER
37 C.F.R. § 1.97(e)

NOTE: A statement must state either: "(1) that each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement, or (2) that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement." 37 C.F.R. § 1.97(e).

Under the first statement under § 1.97(e), it does not matter whether any individual with a duty of disclosure actually knew about any of the information cited before receiving the search report. The date on the communication by the foreign patent office begins the 3-month period in the same manner as the mailing of an Office action starts a 3-month shortened statutory period for reply. See § 609B(5), M.P.E.P., 8th Edition.

CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10*
(When using Express Mail, the Express Mail label number is mandatory;
Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

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37 C.F.R. § 1.8(a)

37 C.F.R. § 1.10 *

☒ with sufficient postage as first class mail.

☐ as "Express Mail Post Office to Addressee"

Mailing Label No. _____ (mandatory)

TRANSMISSION

☐ facsimile transmitted to the Patent and Trademark Office, (703) _____

Signature

Date: _____

Chasidy Smith

(type or print name of person certifying)

* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(c)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

NOTE: "Section 1.97(e) makes it clear that a certification could contain either of two statements. One statement is that each item of information in an information disclosure statement was cited in a search report from a patent office outside the U.S. not more than three months prior to the filing date of the statement. Under this certification, it would not matter whether any individual with a duty actually knew about any of the information cited before receiving the search report. In the alternative, the certification could state that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual having a duty to disclose more than three months prior to the filing of the statement." Notice of January 9, 1992, 1135 O.G. 13-25, at 13. (emphasis added). Thus: "If an item of information is submitted within three months of being cited in a communication from a foreign patent office in a counterpart foreign application, the certification can be properly made regardless of any individual's previous knowledge of the information." *Id.*, 1135 O.G. at 19. See § 609B(5), M.P.E.P., 8th Edition.

NOTE: "The date on the communication by the foreign patent office begins the 3-month period in the same manner as the mailing of an Office action starts a 3-month shortened statutory period for reply. If the communication contains two dates, the mailing date of the communication is the one which begins the 3-month period. The date which begins the 3-month period is not the date the communication was received by a foreign associate or the date it was received by a U.S. registered practitioner. Likewise, the statement will be considered to have been filed on the date the statement was received in the Office, or on an earlier date of mailing or transmission if accompanied by a properly executed certificate of mailing or facsimile transmission under 37 CFR 1.8, or if it is in compliance with the provisions for "Express Mail" delivery under 37 C.F.R. 1.10." See § 609B(5), M.P.E.P., 8th Edition.

NOTE: "The certification can be based on present, good faith knowledge about when information became known without a search of files being made." Thus, for example, the certification of § 1.97(e) does not preclude the use of the certification in an application by corporations whose practitioners have over the years reviewed thousands of patents and technical publications, even though they are unaware of the relevance of any one thereof to the application. Notice of January 9, 1992, 1135 O.G. 13-15, at 19.

See § 609B(5), M.P.E.P., 8th Edition:

"If an information disclosure statement includes a copy of a dated communication from a foreign patent office which clearly shows that the statement is being submitted within 3 months of the date on the communication, the copy will be accepted as the required communication. It will be assumed, in the absence of evidence to the contrary, that the communication was for a counterpart foreign application.

"In the alternative, a statement can be made if no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the statement after making reasonable inquiry, neither was it known to any individual having a duty to disclose more than 3 months prior to the filing of the statement."

NOTE: A copy of the foreign search report need not be submitted with the certification. Notice of April 20, 1992 (1138 O.G. 37-41, 40).

NOTE: "The phrase 'after making reasonable inquiry' makes it clear that the individual making the statement has a duty to make reasonable inquiry regarding the facts that are being certified. The statement can be made by a registered practitioner who represents a foreign client and who relies on statements made by the foreign client as to the date the information first became known. A registered practitioner who receives information from a client without being informed whether the information was known for more than three months, however, cannot make the statement without making reasonable inquiry. For example, if an inventor gave a publication to the attorney prosecuting an application with the intent that it be cited to the Office, the attorney should inquire as to when that inventor became aware of the publication and should not submit a statement under 37 C.F.R. 1.97(e)(2) to the Office until a satisfactory response is received. The statement can be based on present, good faith knowledge about when information became known without a search of files being made." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

See § 609B(5), M.P.E.P., 8th Edition.

NOTE: "Although it is recognized that an individual actually becomes aware of the information in the communication from a foreign patent office sometime after it was mailed, the mailing date of such a communication, if it occurs prior to a first awareness of the same information, would determine the date for filing of an information disclosure statement without a fee" in a certification procedure under § 1.97(e). Notice of January 9, 1992, 1135 O.G. 13-25, at 19 (emphasis added).

NOTE: The mere absence of an item of information from a foreign patent office communication is not intended to represent an opportunity to delay the submission of a item known more than three months prior to the filing of an information disclosure statement to an individual having the duty of disclosure under § 1.56. 62 Fed. Reg. 53,131, 53,150 (Oct. 10, 1997).

NOTE: The IDS is considered filed as of the date it is received in the PTO, or on an earlier date of mailing or transmission if done so with a properly executed certificate of mailing or facsimile transmission under 37 C.F.R. § 1.8, or if it is in compliance with the provisions for "Express Mail" delivery under 37 C.F.R. § 1.10. See § 609B(5), M.P.E.P., 8th Edition.

NOTE: "The certification under § 1.97(e) should be made by a person who has knowledge of the facts being certified. The certification can be made by a practitioner who represents a foreign client and who relies on statements made by the foreign client as to the date the information first became known. A practitioner who receives information from a client without being informed whether the information was known for more than three months, however, cannot make the certification without making reasonable inquiry." Notice of January 8, 1992, 1135 O.G. 13-25 at 19.

NOTE: "The term counterpart foreign patent application means that a claim for priority has been made in either the U.S. application or a foreign application based on the other, or that the disclosures of the U.S. and foreign patent applications are substantively identical (e.g., an application filed in the European Patent Office claiming the same U.K. priority as claimed in the U.S. application)." Notice of April 20, 1992 (1138 O.G. 37-41, 39). See § 609B(5), M.P.E.P., 8th Edition.

NOTE: "Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent or inventor." 37 C.F.R. § 1.56(d) and

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. § 1.56(c).

IDENTIFICATION OF INFORMATION DISCLOSURE STATEMENT FOR WHICH THIS STATEMENT IS BEING MADE

1. This statement is being made for the Information Disclosure Statement

- ☒ accompanying this statement.
☐ filed _____ (date)

STATEMENT

NOTE: A statement under 37 C.F.R. § 1.97(e) need not be in the form of an oath or a declaration under 37 C.F.R. § 1.68. A statement under 37 C.F.R. § 1.97(e) by a registered practitioner or any other individual that the statement was filed within the 3-month period of either the first citation by a foreign patent office or first discovery of the information will be accepted as dispositive of compliance with this provision in the absence of evidence to the contrary. § 609B(5), M.P.E.P., 8th Edition.

2. I, the person(s) signing below state:

- ☐ that each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. 37 C.F.R. § 1.97(e)(1).

NOTE: The three month period starts from the mailing date of the foreign patent office communication. Notice of January 9, 1992, 1135 O.G. 13-25 at 18. The mailing date is the "date on the communication by the foreign patent office." Notice of April 20, 1992 (1138 O.G. 37-41, 38).

OR

- ☐ that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge, after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement. 37 C.F.R. § 1.97(e)(2).

NOTE: "The time at which information 'was known to any individual designated in 37 C.F.R. 1.56(c)' is the time when the information was discovered in association with the application even if awareness of the materiality came later." Notice of April 20, 1992 (1138 O.G. 37-41, 40). Section 609B(5), M.P.E.P., 8th Edition.

IDENTIFICATION OF PERSON(S) MAKING THIS STATEMENT

3. The person making this statement is

(check each applicable item)

- (a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (b) ☐ a person who is substantively involved in the preparation or prosecution of the application, and who is associated with the inventor, with the assignee, or with anyone to whom there is an obligation to assign the application (37 C.F.R. § 1.56(c)) and who signs below.

SIGNATURE OF PERSON MAKING STATEMENT

(type name of person who is signing)

Address of person who is signing

(c) ☒ the practitioner who signs below on the basis of the information:

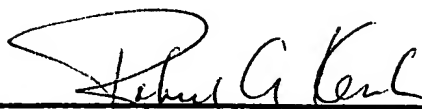
(check each applicable item)

- ☐ supplied by the inventor(s).
- ☐ supplied by an individual designated in § 1.56(c).
- ☒ in the practitioner's file.

Reg. No.: 28,626

Tel. No. (580) 251-3125

Customer No.:



SIGNATURE OF PRACTITIONER

Robert A. Kent

(type or print name of practitioner)

P.O. Box 1431

P.O. Address

Duncan, OK 73536-0440

PTO-1449 Information Disclosure Citation in an Application	Application No. 10/650,101	Applicant(s): Bradley L. Todd et al.	
	Docket Number 2001-IP-005443U2	Group Art Unit 1712	Filing Date 08/26/2003

U.S. PATENT DOCUMENTS

DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE
5,607,905	03/04/97	Dobson, Jr. et al.	507	211	03/15/94
6,131,661	10/17/00	Conner, et al.	166	300	12/04/98
6,143,698	11/07/00	Murphey, et al.	507	145	12/04/98
6,394,185 B1	05/28/02	Constien	166	296	07/27/00
6,761,218 B2	07/13/04	Nguyen et al.	166	278	04/01/02
US 2002/0036088 A1	03/28/02	Todd	166	300	01/09/01
US 2002/0125012 A1	09/12/02	Dawson et al.	166	300	01/08/02
US 2005/0006095 A1	01/13/05	Justus, et al.	166	295	07/08/03

NON-PATENT DOCUMENTS

DOCUMENT (Including Author, Title, Source, and Pertinent Pages)	DATE
SKRABAL ET AL., <i>THE HYDROLYSIS RATE OF ORTHOFORMIC ACID ETHYL ETHER</i> , CHEMICAL INSTITUTE OF THE UNIVERSITY OF GRAZ, PAGES 1-38	01/13/21
Heller, et al., <i>Poly(ortho esters) – From Concept To Reality</i> , Biomacromolecules, Vol. 5, No. 5, 2004 (pp. 1625-1632)	05/09/79
Schwach-Abdellaoui, et al., <i>Hydrolysis and Erosion Studies of Autocatalyzed Poly(ortho esters) Containing Lactoyl-Lactyl Acid Dimers</i> , American Chemical Society, Vol. 32, No. 2, 1999 (pp. 301-307)	
Ng, et al., <i>Synthesis and Erosion Studies of Self-Catalyzed Poly(ortho ester)s</i> , American Chemical Society, Vol. 30, No. 4, 1997 (pp. 770-772)	
Ng, et al., <i>Development Of A Poly(ortho ester) prototype With A Latent Acid In The Polymer Backbone For 5-fluorouracil Delivery</i> , Journal of Controlled Release 65 (2000), (pp. 367-374)	
Rothen-Weinhold, et al., <i>Release of BSA from poly(ortho ester) extruded thin strands</i> , Journal of Controlled Release 71, 2001, (pp. 31-37)	
Heller, et al., <i>Poly(ortho ester)s – their development and some recent applications</i> , European Journal of Pharmaceutics and Biopharmaceutics, 50, 2000, (pp. 121-128)	
Heller, et al., <i>Poly(ortho esters); synthesis, characterization, properties and uses</i> , Advanced Drug Delivery Reviews, 54, 2002, (pp. 1015-1039)	
Heller, et al., <i>Poly(ortho esters) For The Pulsed And Continuous Delivery of Peptides And Proteins</i> , Controlled Release and Biomedical Polymers Department, SRI International, (pp. 39-46)	
Zignani, et al., <i>Subconjunctival biocompatibility of a viscous bioerodable poly(ortho ester)</i> , J. Biomed Mater Res, 39, 1998, pp. 277-285	
Toncheva, et al., <i>Use of Block Copolymers of Poly(Ortho Esters) and Poly (Ethylene Glycol)</i> , Journal of Drug Targeting, 2003, Vol. 11(6), pp. 345-353	

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

PTO-1449 Information Disclosure Citation in an Application	Application No. 10/650,101	Applicant(s): Bradley L. Todd et al.	
	Docket Number 2001-IP-005443U2	Group Art Unit 1712	Filing Date 08/26/2003

	Schwach-Abdellaoui, et al., <i>Control of Molecular Weight For Auto-Catalyzed Poly(ortho ester) Obtained by Polycondensation Reaction</i> , International Journal of Polymer Anal. Charact., 7: 145-161, 2002, pp. 145-161	
	Heller, et al., <i>Release of Norethindrone from Poly(Ortho Esters)</i> , Polymer Engineering and Science, Mid-August, 1981, Vol. 21, No. 11 (pp. 727-731)	

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.	